

Practitioner's Docket No. 1062/E13

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kamen et al.

Application No.: 10/803,049

Group No.: 3742

Filed: 03/16/2004

Examiner: Fastovsky, Leonid M.

For: Cassette and Method for Drug Preparation and Delivery

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))

TIME OF TRANSMITTAL OF ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either

(1) a final action under § 1.113 or

(2) a notice of allowance under § 1.311

whichever occurs first.

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*;
Express Mail certification is *optional*.)

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☒ deposited with the United States Postal Service in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

☒ with sufficient postage as first class mail.

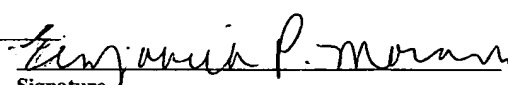
37 C.F.R. § 1.10*

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TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____


Signature

Date: March 18, 2005

Elizabeth P. Morano
(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

STATEMENT

FEE

2. Accompanying this transmittal is the fee for submission of an information disclosure statement under section 1.97(c). (\$180.00)

FEE PAYMENT

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$180.00).

Fee due \$180.00

METHOD OF PAYMENT OF FEE

4. Attached is a check in the amount of \$180.

Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

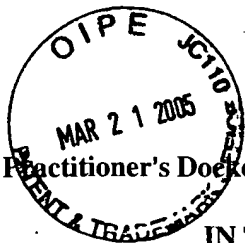
A duplicate of this paper is attached.

DATE: March 18, 2005



Elizabeth P. Morano
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110-1618
US

01062/00E13 370922.1



1FW\$

Practitioner's Docket No. 1062/E13 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____

Inventor(s)

for _____

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: **Kamen et al.**

Application No.: **10/803,049**

Group No.: **3742**

Filed: **3/16/2004**

Examiner: **Fastovsky, Leonid M.**

For: **Cassette and Method for Drug Preparation and Delivery**

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 11)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

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TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature Elizabeth P. Morano

Date: March 18, 2005

Elizabeth P. Morano

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

INFORMATION DISCLOSURE STATEMENT

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☒ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Dean Kamen, Charles M. Grinnell, Attorney Docket: 1062/E13
 Marc A. Mandro, Dennis Gilbreath,
 Kevin Lee Grant, Jason A. Demers,
 William T. Larkins, Robert Manning,
 and Richard J. Lanigan

Serial No: 10/803,049 Art Group Unit: 3742

Date Filed: 03/16/2004 Examiner Name: Fastovsky, L.

Invention: Cassette and Method for Drug Preparation and Delivery

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANTS' INFORMATION DISCLOSURE STATEMENT**

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AA	US 1,792,906	2/17/1931	Heilos	251/209
	AB	US 2,526,017	10/17/1950	Igg	251/209
	AC	US 2,902,253	9/1/1959	Page	251/209
	AD	US 3,540,694	11/17/1970	Cornelius	251/209
	AE	US 3,570,486	3/16/1971	Engelsher, et al.	128/218
	AF	US 3,722,858	3/27/1973	Sugimoto, et al.	251/209
	AG	US 3,727,882	4/17/1973	Burris, et al	251/209
	AH	US 4,042,153	8/16/1977	Calahan et al.	222/207
	AI	US 4,230,300	10/28/1980	Wiltse	251/205
	AJ	US 4,236,880	12/2/1980	Archibald	417/478
	AK	US 4,277,226	7/7/1981	Archibald	417/38
	AL	US 4,303,376	12/1/1981	Siekman	417/360
	AM	US 4,534,764	8/13/1985	Mittleman, et al.	604/81
	AN	US 4,573,994	3/4/1986	Fischell, et al.	604/891
	AO	US 4,576,211	3/18/1996	Valentini, et al.	141/319
	AP	US 4,648,868	3/10/1987	Hardwick, et al.	604/32
	AQ	US 4,667,927	5/26/1987	Oscarsson	251/209
	AR	US 4,696,671	9/29/1987	Epstein, et al.	604/6

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AS	US 4,721,138	1/26/1988	Simonazzi	141/150
	AT	US 4,804,366	2/14/1989	Zdeb, et al.	604/85
	AU	US 4,807,660	2/28/1989	Aslanian	137/382
	AV	US 4,818,186	4/4/1989	Pastrone, et al.	417/63
	AW	US 4,850,978	7/25/1989	Dudar, et al.	604/201
	AX	US 4,925,444	5/15/1990	Orkin et al.	604/250
	AY	US 4,976,162	12/11/1990	Kamen	73/865.9
	AZ	US 5,005,604	4/9/1991	Aslanian	137/556
	BA	US 5,006,050	4/9/1991	Cooke, et al.	417/478
	BB	US 5,045,068	9/3/1991	Kawai, et al.	604/246
	BC	US 5,062,774	11/5/1991	Kramer et al.	417/413
	BD	US 5,088,515	2/18/1992	Kamen	137/15
	BE	US 5,098,262	3/24/1992	Wecker, et al.	417/479
	BF	US 5,113,904	5/19/1992	Aslanian	137/556
	BG	US 5,116,316	5/26/1992	Sertic, et al.	604/83
	BH	US 5,122,116	6/16/1992	Kriesel, et al.	604/89
	BI	US 5,156,186	10/20/1992	Manska	137/556
	BJ	US 5,292,306	3/8/1994	Wynkoop et al.	604/51
	BK	US 5,302,093	4/12/1994	Owens et al.	417/474
	BL	US 5,330,426	7/19/1994	Kriesel, et al.	604/89
	BM	US 5,378,126	1/3/1995	Abrahamson, et al.	417/479
	BN	US 5,385,540	1/31/1995	Abbott, et al.	604/4
	BO	US 5,401,059	3/28/1995	Ferrario	283/67
	BP	US 5,478,337	12/26/1995	Okamoto, et al.	604/413
	BQ	US 5,584,671	12/17/1996	Schweitzer, Jr., et al.	417/298
	BR	US 5,588,816	12/31/1996	Abbott, et al.	417/479
	BS	US 5,593,290	1/14/1997	Greisch, et al.	417/478
	BT	US 5,649,810	7/22/1997	Schweitzer, Jr., et al.	417/298
	BU	US 5,651,775	7/29/1997	Walker, et al.	604/207
	BV	US 5,681,285	10/18/1997	Ford, et al.	604/151
	BW	US 5,713,865	2/3/1998	Manning, et al.	604/122
	BX	US 5,716,343	2/10/1998	Kriesel, et al.	604/132
	BY	US 5,755,683	5/26/1998	Houle, et al.	604/30

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	BZ	US 5,758,095	5/26/1998	Albaum, et al.	395/202
	CA	US 5,776,103	7/7/1998	Kriesel, et al.	604/132
	CB	US 5,816,779	10/6/1998	Lawless, et al.	417/63
	CC	US 5,879,328	3/9/1999	Holmberg, et al.	604/82
	CD	US 6,165,154	12/26/2000	Gray et al.	604/153
	CE	US 6,210,361	10/15/02	Kamen et al.	604/131
	CF	US 6,234,997	5/22/01	Kamen et al.	604/82
	CG	US 6,464,667	10/15/02	Kamen et al.	604/82
	CH	US 6,726,656 B2	4/27/04	Kamen et al.	604/131
	CI	08/478,065	6/1995	Houle et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Sub-class
	CJ	DE	58,977	26 November 1890	Voss	47
	CK	BE	535,179	15 February 1955	L'Auxiliaire de L'Industrie et des Mines "Auxim"	F 06 K
	CL	FR	2.138.617	5 January 1973	Standayne, Inc.	F16J 15/00
	CM	FR	2 340 491	2 September 1977	Puig, Juan Marti	F16K 5/00
	CN	GB	2 053 378 A	4 February 1981	Baxter Travenol	F04B 43/02
	CO	EP	0 154 191 A1	11 September 1985	OMNI-Flow, Inc.	A61M 5/14
	CP	EP	0 222 088 A2	20 May 1987	OXIMETR IX, Inc.	A61M 5/14
	CQ	DE	36 05 640 A1	27 August 1987	Grässle Maschinenbau	B67C 1/06
	CR	EP	0 293 592	7 December 1988	Abbott Laboratories	A61M 5/14

Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/ Sub- class
	CS	EP	0 335 378 A2	4 October 1989	NISSHO Corporation	A61J 1/00
	CT	WO	93/12825	8 July 1993	Abbott Laboratories	A61M 1/00
	CU	WO	93/23096	25 November 1993	Elan Medical Technologies, Inc.	A61M 5/155
	CV	WO	94/08549	28 April 1994	Abbott Laboratories	A61J 1/00
	CW	WO	94/12235	9 June 1994	Abbott Laboratories	A61M 31/00
	CX	WO	94/27669	8 December 1994	Science Incorporated	A61M 37/00
	CY	FR	2 717 919 A1	29 September 1995	ENSYMA	G06F 7/60
	CZ	WO	95/29455	2 November 1995	Fillingane, Sam	G06F 159/00
	DA	WO	96/13790	9 May 1996	Med-E- Systems Corporation	G06F 159/00
	DB	WO	96/40328	19 December 1996	DEKA Products L.P.	A61M 5/168
	DC	WO	97/04712	13 February 1997	MC Medical Card Systems GmbH	A61B 19/00

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	DD	EDMOND, ET AL.	"Prevention of Mis-Prescribing in the Elderly : A Potential Use for Micro-Computers," Proceedings of the 8th Annual Symposium on Computer Applications in Medical Care, Washington, DC, USA, November 4-7, 1984, pp. 357-360
	DE	OGURA, ET AL.	"One-line prescription order and prescription support in an integrated hospital information system," Med. Inform. (1985) Vol. 10, No. 4, pp. 287-299
	DF	MOLIVER, ET AL.	"Decision Support for Medical Treatment: A TPN Prescription System on a Central Hospital Computer," Proceedings of the 11th Annual Symposium on Computer Applications in Medical Care, Washington, DC, USA, November 1-4, 1987, pp. 246-254
	DG	OGURA, ET AL.	"Online support functions of prescription order system and prescription audit in an integrated hospital information system," Med. Inform. (1988), Vol. 13, No. 3, pp. 161-169
	DH	BAZARAL, ET AL.	"Recommendations for Specifications and Operator Interface Design for New Medical Infusion Pumps," Biomedical Instrumentation & Technology (Sep./Oct. 1992), 2:364-370

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

NOTE: *"A copy of any patent, publication or other information listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120." 37 C.F.R. section 1.98(d).*

WARNING: *"This exception to the requirement for copies of information does not apply to information which was cited in an international application under the Patent Cooperation Treaty." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

WARNING: *"Information which is cited or submitted to the Office in the parent application of a file wrapper continuing application under 37 C.F.R. section 1.62 will be part of the file before the examiner and need not be resubmitted in the continuing application. Likewise, the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application and thus this information need not be resubmitted unless applicant desires the information to be printed on the patent." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

WARNING: *While a copy of a non-English language item of information need not be submitted, if it was previously submitted to, or cited by, the Office in a prior application, provided it is properly identified in this statement and this application relies on that earlier filing date under 35 U.S.C. 120, nevertheless, the requirement in section 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. The concise explanation must explain the relevance, as presently understood by the person designated in section 1.56(c) most knowledgeable about the content of the information. Notice of January 9, 1992, 1135 O.G. 13-25, at 20.*

The present application is a continuation of application serial number 10/266,997 (now U.S. Patent No. 6,726,656) filed October 8, 2002, which is a continuation of application Serial No. 09/359,322 (now U.S. Patent No. 6,404,667), filed July 22, 1999, which is a divisional of application Serial No. 09/137,025 (now U.S. Patent No. 6,210,361), filed August 20, 1998, which in turn is a continuation-in-part of U.S. Patent Application Nos. 08/916/890 (abandoned) and 08/917,537 (now U.S. Patent No. 6,165,154), both of which were filed August 22, 1997.

All references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application:

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

☒ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

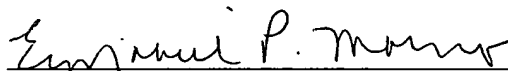
☒ in the practitioner's file.

Date: March 18, 2005

Reg. No.: 42,904

Tel. No.: (617) 443-9292

Customer No.: 002101



SIGNATURE OF PRACTITIONER

Elizabeth P. Morano

(type or print name of practitioner)

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110

01062/00E13 370368.1